Exhibit 519 [replacing Dkt. #2364-74] attached to Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO and OCPA Claims at Dkt. #2182.

- Redaction withdrawn by Defendant

PSJ3

Exhibit 519

From: Freitas, Kristen [kfreitas@hdmanet.org]
Sent: 3/15/2013 8:36:03 PM
To: Freitas, Kristen [kfreitas@hdmanet.org]
Subject: Feedback requested - Hydrocodone follow-up

Importance: High

To: Federal Government Affairs Committee and Regulatory Affairs Committee

Please do not circulate outside of your company.

Yesterday on our FGAC call, we discussed the current politics surrounding a potential legislative carve-out on the rescheduling of hydrocodone combination products. We expect the House and Senate bills to be introduced next week with a three-year phase-in. Given the circumstances we discussed, here is what we are proposing for how we position HDMA in the short term for our messaging on the hill.

Recommendation:
1) We need to provide feedback **within a few days** to the bill sponsors on their question to us about the adequacy of the 3-year phase-in. House and Senate cosponsors have indicated a willingness to adjust the time period taking into account our recommendations. If more time is necessary, please let us know how much time you anticipate it would take. We believe more than 5 years may be a challenge.
2) However, we will not change our message and will continue to educate legislators about the policy justifications for full carve-out. Currently, the political realities make full exemption extremely difficult, based on the conversations we have had on the hill, but we will continue our efforts. It is our understanding that DEA is pushing back strongly on any possible exemption in legislation.
3) We will let the bill sponsors know that a carve-out is the only way to address all of our concerns, but we greatly appreciate their willingness to incorporate a phase-in as a starting point.
4) While we will not endorse/support the bill, we will not oppose it. We wish to continue working with the sponsors, not in opposition.

Because this is such a sensitive and complex issue, I did not include much detail in this email about our hill conversations. I am happy to discuss off-line if you have concerns or questions. **Please let me know by Tuesday at noon your thoughts on a time frame and if you have any concerns about this approach. Please coordinate internally within your companies so that we have one response per company.**

Article - There was an article entitled, "Don't Expect Quick Action on Painkillers, FDA Tells Lawmakers" printed yesterday in The Hill (inside the beltway publication) which reported on a letter that FDA recently sent to the bill sponsors indicating that a number of regulatory hurdles remain before hydrocodone can be reclassified. We are in the process of trying to get more information on FDA's approach. Based on the hill meetings we have had, there seems to be a sense that FDA may move to reschedule, but nothing is definitive.

Dr. Throckmorton - Anita mentioned on the FGAC call yesterday that she would be attending a Pain Care Forum meeting with Dr. Throckmorton. Below is her summary.

This is to summarize the additional information from FDA regarding rescheduling hydrocodone combination products that I learned by attending a Pain Care Forum (PCF) meeting today. Dr. Doug Throckmorton, Deputy Director of CDER and heading up the FDA review of hydrocodone combination products, was a guest speaker.

Dr. Throckmorton gave an overview of the current status of multiple FDA efforts on controlled substances. In addition to hydrocodone combination products, he covered abuse deterrent formulations, the LA/EF REMS, FDA's educational activities, environment/disposal, and other topics.

Dr. Throckmorton stated that FDA's next steps for reviewing rescheduling hydrocodone combination included:

- FDA will review the transcript of the Drug Safety and Risk Management Advisory (DSaRM) Committee Meeting held in January (where the DSaRM voted in favor of "upscheduling"). Will also review/summarize the written Docket submissions (comments were due Feb. 1 – HDMA had submitted comments.)
- Three offices within CDER are re-reviewing their original analyses in light of the DSaRM meeting and new docket information. They include the Offices of: Controlled Substances, Epidemiology and New Drug Review. They are to determine if their original recommendations, (i.e., the data do not support "upscheduling") should be revised.
- They are to provide their recommendations, including whether they now believe upscheduling is appropriate, to Dr. Throckmorton, who will then share it with Janet Woodcock. Dr. Woodcock is the Director of CDER.
- Dr. Throckmorton stated they're still determining, internally, what the next steps in the process would be after Dr. Woodcock has the staff's recommendation.
- Additionally, he would not give a decision timeline, other than to state that Dr. Woodcock had asked him to move the re-review along and get her recommendations "very quickly" but would not indicate what that deadline was. Additionally, he would not speculate how long it would take for FDA to make their final decision after that.

When asked if FDA was willing to meet with stakeholder groups, Dr. Throckmorton stressed that FDA would consider meeting requests but that they wanted a "transparent" process. He stated that several groups had made such requests and that they were considering at least one of them. However, he made no specific commitment to such meetings, again emphasizing that FDA had been very careful to make sure this was a public process [by holding the DSaRM meeting and creating a written docket] and they wanted to continue along those lines. So, he did not commit to holding additional meetings nor did he deny them.

In a sidebar after the meeting, I asked about a meeting request from HDMA, and he stated such a request could go directly to him (in writing), but again, did not commit one way or the other.

Kristen LaRose Freitas
Senior Director, Federal Government Affairs
Healthcare Distribution Management Association
901 N. Glebe Rd., Suite 1000
Arlington, VA 22203
703-885-0232 – phone
703-812-5282 – fax
kfreitas@hdmanet.org